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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,736	09/21/2006	Claudia Bedard	BED001	7789

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DIEDERIKS & WHITELAW, PLC
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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,736	BEDARD ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10202005</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robitaille et al. (US 2002/0085950) in view of Hennebert et al. (US 4,764,351).

With respect to claims 1, 6, 7, and 8-10, claims 1 and 6 are written in Jepson claim format, which is an admission that the limitations recited in the preambles up to the phrase “the improvement comprising,” are considered to be known prior art. In any event, Robitaille et al. teaches essentially the claimed method wherein an article to be sterilized may be exposed to repeated cycles of a vacuum (0.5-2 mbar) followed by humidified ozone. See Figure 3; paragraphs [0013]-[0032]. The sterilization chamber is maintained at a temperature of 20-35 °C (paragraph [0053]). Robitaille et al. further discloses that “the high relative humidity level combined with temperature differentials between walls and/or the load may lead to water condensation.” See paragraph [0039]. Robitaille et al. is silent with respect to removing

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condensation during the sterilization cycle between successive exposures to the humidified ozone.

Hennebert et al. discloses a method of gaseous sterilization and teaches that “the damaging role of water condensation has also been demonstrated. Some manufacturers of apparatuses for low temperature sterilization have tried to avoid the problems due to water condensation by automatically purging condensates during the sterilization cycle.” See col.2, lines 1-6. As Hennebert et al. evidences that it was known in the art at the time of the invention to remove condensates using automatic purges throughout the sterilization cycle, it would have been obvious to do the same in the method of Robitaille et al. as an additional means to avoid the problems associated with water condensation. One would have had an expectation of success when making the combination.

With respect to claims 2-4 and 11-13, Hennebert et al. does not teach how the condensate is purged. However, Robitaille et al. already discloses a method of removing humidity at the end of the sterilization cycle by flushing with repeated pulses of oxygen. See paragraph [061]. It would have been obvious to use this same means of removing condensates in the manner suggested by Hennebert et al..

As to claims 5 and 14, Robitaille et al. discloses temperature equalization at the beginning of the sterilization process but not between cycles. See paragraph [0030]. However, as Robitaille et al. also teaches that temperature differentials are a cause of water condensation (paragraph [0039]), it would yielded predictable results to also equalize the temperature between cycles as a further means of reducing water condensation.

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Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh McKane

**Leigh McKane
Primary Examiner
Art Unit 1744**

elm
6 August 2007